REMARKS

Claims 35-41, 43-47 and 69-73 are now pending. Claims 35, 41, 43-46 and 69 are amended and claims 70-73 are added herein.

The courtesies extended to Applicants' representative by Examiner Sisson at the interview held January 21, 2004, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below and constitute Applicants' record of the interview.

The Declaration is objected to under 37 C.F.R. §1.67(b) because the pending claims allegedly no longer substantially embrace the invention as set forth in the statement of the invention and/or in the original claims. Although Applicants disagree with the assessment that the pending claims no longer substantially embrace the invention as set forth in the statement of the invention and/or in the original claims, in an effort to expedite allowance of the present application, a supplemental Declaration is filed herewith. Therefore, the objection should be reconsidered and withdrawn.

The specification is objected to because the title is allegedly not descriptive. The title is amended herein in order to clearly describe the present invention. Therefore, the objection should be reconsidered and withdrawn.

Claims 40, 41 and 43-47 are objected to for allegedly being of improper dependent form for failing to further limit the subject matter of the previous claim. In view of the above amendments to claims 41, 43 and 44, it is respectfully submitted that claims 40, 41 and 43-47 are proper dependent claims.

In particular, the recitation in claims 40 and 41 of DNA is not inconsistent with the statement in claim 35 that the claimed method is conducted "in the absence of deoxyribonucleoside triphosphates." DNA is not a deoxyribonucleoside triphosphate. DNA may be synthesized by polymerizing deoxyribonucleoside triphosphate in which covalent

phosphodiester linkages, i.e., covalent linkages, are formed with simultaneous release of pyrophosphate groups. Thus, although DNA is formed from deoxyribonucleoside triphosphates, it does not contain deoxyribonucleoside triphosphates. As a result, the recitation in claims 40 and 41 of DNA is not inconsistent with the recitation in claim 35 that the method is conducted in the absence of deoxyribonucleoside triphosphates.

Claims 43 and 44 have been amended to clarify that the RNA polymerase is a T7-like phage polymerase selected from the group consisting of T7 RNA polymerase, T3 RNA polymerase and SP6 RNA polymerase. As amended, it is respectfully submitted that claims 43 and 44, and thus claims 45 and 46, properly depend from claim 35.

It is also respectfully submitted that claim 47 does not broaden the scope of claim 35. In fact, no basis for including this claim in the objection has been set forth.

Claims 40, 41 and 43-47 are proper dependent claims. Therefore, the objection of these claims under 37 C.F.R. §1.75(c) should be reconsidered and withdrawn.

Claims 35-41, 43-47 and 69 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. Applicants respectfully traverse the rejection.

In particular, it is argued that "[a] review of the disclosure finds that the promoter must be double stranded DNA." As noted in the specification on page 3, lines 4-7, the term "promoter" is defined as "a double-stranded nucleotide sequence ..." In addition, the promoter used in the method of claim 35 is clearly double-stranded. See the description of the reagent in claim 35. However, to clarify that the promoter is double-stranded, reference to "transcription under the control of a promoter" has been moved to the bottom of the claim and the term "promoter" has been replaced by "the double-stranded promoter". However, it is respectfully submitted that the amendment to claim 35 does not change the scope of claim 35. Instead, what was previously at least implicit in claim 35, i.e., that the reagent containing the

double-stranded promoter acts as a promoter to promote amplification of the RNA target sequence by transcription, is now explicitly recited in claim 35.

With regard to the allegation that the promoter must be a DNA sequence, the Patent Office is directed to the repeated use in the specification of the phrase nucleotide sequence rather than DNA in describing promoters that can be used in the present invention. In fact, as described on page 7, lines 30-38, and claimed in claim 40, the specification clearly describes that the first and third segments of the reagent may consist of DNA, clearly indicating that they may not consist of DNA. Therefore, it is respectfully submitted that a full review of the disclosure clearly indicates that the promoter is a double-stranded nucleotide sequence, but need not be double-stranded DNA.

In addition, it is respectfully submitted that the specification provides written description for the nucleotide segments of claim 35. As defined in claim 35, the first nucleotide segment is of a sufficient length that it can play the role of sense strand of a promoter for the RNA polymerase. However, the first nucleotide segment need not contain at least 9 nucleotides. In particular, the recitation to at least 9 nucleotides on page 7 of the specification only describes a specific embodiment of the present invention, which is now claimed in new claim 70. In particular, the specification clearly says that "[a]ccording to a specific embodiment, the first segment contains at least 9 nucleotides" (emphasis added). The next paragraph of the specification goes on to indicate that shorter sequences can be used. Thus, it is clear that the Applicants did not intend the invention to be limited to embodiments where the first segment contains at least 9 nucleotides. Instead, as defined in claim 35, the first segment must be of sufficient length to play the role of sense strand of a promoter of the RNA polymerase. As long as the first segment meets this requirement, no specific length is required.

Similarly, the second nucleotide segment must be of a sufficient length to hybridize with a region of the RNA that comprises the target sequence. Furthermore, the third nucleotide segment must be of a sufficient length to hybridize with the first segment so as to form with it a functional double-stranded promoter. The specification clearly provides written description for nucleotide strands having these properties.

As noted in the Office Action, many promoter sequences specific for T7-like phage RNA polymerases exhibit high homology. It is also noted that the natural promoters specific for these RNA polymerases are well known. Page 4, line 37 - page 5, line 1. Based on the fact that these natural promoters are well known and highly homologous, it is respectfully submitted that the present specification clearly provides written description for the present claims. In particular, the reagent of claim 35 is narrowly tailored to encompass reagents containing a first nucleotide strand comprising a first nucleotide segment capable of playing the role of sense strand of a promoter for the RNA polymerase, i.e., for the T7-like phage RNA polymerase of claim 35. Based on the knowledge of one of ordinary skill in the art with regard to promoters for this RNA polymerase, it is respectfully submitted that the present specification clearly provides written description for this feature of claim 35. In particular, it is not necessary for the specification to specifically set forth the various promoters based on the extensive knowledge that one of ordinary skill in the art has with regard to the claimed promoters.

Claims 35-41, 43-47 and 69 are also rejected for failing to place a limit on the length of the fourth segment. It is respectfully submitted that it is improper to reject claim 35, as well as claims 43-47 and 69, on this basis since they do not even recite the fourth segment. With regard to claim 36 and claims dependent thereon, it is respectfully submitted that the recitation of a fourth segment having from 1 to 18 nucleotides merely describes an embodiment of the invention. In particular, the specification specifically indicates that the

recitation of 1 to 18 nucleotides is merely an example of an appropriate amount of nucleotides that may be contained in the fourth segment. The specification clearly does not limit the fourth segment to sequences containing 1 to 18 nucleotides. Instead, longer nucleotide segments can be used as long as the fourth segment is shorter than the second segment of the first strand, as described in claim 36.

The present specification provides written description for the present claims. Therefore, the rejection under 35 U.S.C. §112, first paragraph, should be reconsidered and withdrawn.

Claims 35-41, 43-47 and 69 are rejected under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

With regard to the rejection of the phrase "T7-like phage RNA polymerase," it is respectfully submitted that the specification provides a definition of the type of RNA polymerases covered by this expression at page 4, line 30 - page 5, line 23. In particular, the specification explains that these RNA polymerases are very simple enzymes that are highly homologous to one another and consist of a single subunit. It is also indicated that these RNA polymerases recognize promoters having a consensus sequence from position -17 to position +6, and in particular from position -17 to position -1.

As set forth in the Declaration of Dr. McAllister filed January 23, 2003, one of ordinary skill in the art would have understood that RNA polymerases encoded by bacteriophage T7 and its relatives have many common structural and functional features. In particular, the promoter sequences recognized by these phage polymerases, such as T7, T3, K11, SP6 and BA14 phage polymerases, all share a common 23 base pair consensus sequence between nucleotides -17 to +6. Because of the structural and functional similarities of the RNA polymerases encoded by these bacteriophages, Dr. McAllister notes that those skilled in the art refer to these RNA polymerases as "T7-like RNA polymerases." Thus, referring to the

claimed RNA polymerase as a "T7-like phage polymerase" would clearly have been understood by one skilled in the art as referring to the RNA polymerases encoded by T7 and its related phages.

In view of the definition set forth in the specification and Dr. McAllister's comments, it is respectfully submitted that the phrase "T7-like phage RNA polymerase" would be understood by one of ordinary skill in the art.

With regard to the phrase "an absence of deoxyribonucleoside triphosphates," it is respectfully submitted that this phrase would also be understood to one of ordinary skill in the art. In particular, as discussed above, this phrase would not be understood to read on DNA, which as noted in the Office Action is specifically recited in claim 46. Instead, deoxyribonucleoside triphosphates clearly refers to a monomer used in forming DNA, but not to DNA itself.

Claim 45 has been amended to include the SEQ ID NO of amino acids 625 to 652 of the T7 RNA polymerase sequence. Thus claim 45 clearly recites that the claimed RNA polymerase contains at least one mutation in the region corresponding to this sequence.

The term "better" in claim 46 has been replaced by the term "higher." It is respectfully submitted that one of ordinary skill in the art would understand the meaning of "a higher yield."

With regard to claim 69, it is respectfully submitted that the meaning of the position numbers used in this claim is well known to those skilled in the art. In addition, it is also specifically described on page 3 of the specification. However, claim 69 has been amended to specifically recite this meaning based on the Examiner's helpful suggestion made during the interview.

The claims clearly recite the invention. Therefore, the rejection under 35 U.S.C. §112, second paragraph, should be reconsidered and withdrawn.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 35-41, 43-47 and 69-73 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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WPB:MLM/jam

Attachment:
Supplemental Declaration

Date: January 29, 2004

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